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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/147,443

01/21/1999

ANDREAS MORELL

P63221US0

1730

7590

08/06/2004

BETH A BURROUS  
FOLEY & LARDNER  
WASHINGTON HARBOUR  
3000 K STREET NW SUITE 500  
WASHINGTON, DC 20007-5143

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/147,443	Applicant(s) MORELL ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22, 23 and 25-44 is/are pending in the application.  
     4a) Of the above claim(s) 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22, 23 and 25-32 is/are allowed.
- 6) ☒ Claim(s) 33 and 36-43 is/are rejected.
- 7) ☒ Claim(s) 34 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05062004</u> | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/EP97/03253.

Claims 1-21 and 24 have been canceled.

Claims 22, 23, and 25-44 are currently pending.

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 22-32, in the Paper filed October 22, 2003 is again acknowledged.

Upon further review **the restriction requirement between Groups I & II is hereby withdrawn.** In view of the fact that the recited heavy chain segments and recited light chain segments overlap in the claims, both the heavy chain and light chain sequences must be searched. Accordingly, no further burden is required to search the invention of Group II, claims 33-43, along with that of Group I.

Applicant's election without traverse of the light chain species defined as SEQ ID NO: 60 is acknowledged. Upon further review the species requirement is withdrawn.

2. Claim 44 **stands withdrawn from further consideration** pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed October 22, 2003.

Accordingly, **claims 22, 23 and 25-43 are the subject of examination** in the present Office Action.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 33 and 36-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Dziegiel et al (J. Imm. Meth. [1995] 182:7-19; AO on form PTO-1449 filed March 1, 1999, of record).

Dziegiel teaches a purified polypeptide that binds to the rhesus D erythrocyte surface antigen (Abstract in particular). Dziegiel teaches that the polypeptide is an Fab fragment [claim 36] of an immunoglobulin comprising both V<sub>H</sub> and V<sub>L</sub> regions that specifically binds to Rhesus D antigen (page 10, paragraph bridging columns in particular)[claim 37]. Accordingly, the polypeptide satisfies the metes and

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bounds of the limitation in claim 33 that the polypeptide is "a functional variant" of SEQ ID NO: 60. Applicant is reminded that the "function" of any antibody is to bind to an antigen. Accordingly, any antibody that binds to rhesus D antigen polypeptide satisfies the metes and bounds of the limitation "functional variant" in the claim. Dziegiel teaches that the antibody was engineered from a monoclonal human antibody of the IgG1 subclass (page 10, paragraph bridging columns in particular)[claim 38]. Dziegiel teaches that the nucleic acid sequences encoding the immunoglobulin fragment were obtained using standard methods (page 14, first paragraph of first column in particular)[claim 39]. Dziegiel teaches the formulation of the Fab polypeptides in phosphate-buffered saline, a pharmaceutically acceptable carrier (page 14, second paragraph of first column in particular)[claims 40-41]. Dziegiel teaches that the Fab can be used for typing rhesus D antigen (Table 4 in particular)[claims 42-43]. The prior art teaching anticipates the claimed invention.


#### *Conclusion*

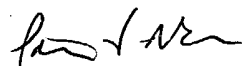
4. Claims 34 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.   
Patent Examiner  
August 4, 2004

  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER  
8/4/04